

Message Text

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70

ORIGIN HEW-06

INFO OCT-01 EA-09 ISO-00 OES-05 /021 R

DRAFTED BY: DHEW/FDA:JRWEINROTH MD

APPROVED BY: OES/APT/BMP:MBEAUBIEN

DHEW/OIH:MACODDING

EA/IMS:DTKENNEY INFO

EA/PRCM:PGSMITH INFO

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R 010123Z JAN 76

FM SECSTATE WASHDC

TO AMEMBASSY JAKARTA

AMCONSUL HONG KONG

UNCLAS STATE 000198

E.O. 11652: NA

TAGS: OGEN, ETRD, TBIO, ID, HK

SUBJ: FDA ADVISORY-VOLUNTARY RECALL, LACK OF ASSURANCE
OF STERILITY

1. FDA ADVISES THAT:

PRODUCT INVOLVED: PRINCIPEN/N STERILE SODIUM AMPICILLIN U.S.P.
INJECTIONS IN 500 MG. AND 1 GRAM VIALS. INJECTIONS ARE TO BE
ADMINISTERED IM OR IV. PRODUCT COMES IN CARTONS OF TEN VIALS
AND CONTAINS INSERT. CASE CONSISTS OF 500 OR 100 VIALS.

LOT NUMBERS INVOLVED: 500 MG PRODUCT-LOTS 4D511, 4H594,
5A483. (NDC-0003-0983-26). 1 GRAM PRODUCT-LOTS 4C619,
4D510, 4G449, 4L578, 5A520. (NDC-0003-0965-31).

MANUFACTURER:

E.R. SQUIBB AND SONS, INC
GEORGES ROAD
NEW BRUNSWICH, NEW JERSEY 08903

RECALLING FIRM:

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E.R. SQUIBB AND SONS, INC
PRINCETON, NEW JERSEY 08540

REASON FOR ADVISORY: AS A RESULT OF A COMPREHENSIVE ESTABLISHMENT INSPECTION, IT WAS REVEALED THAT THE FIRM WAS UTILIZING PENNOXIDE GAS AS A PRECAUTIONARY MEASURE IN THE MANUFACTURE OF SODIUM AMPICILLIN AND AS THE SOLE METHOD OF STERILIZATION OF BATCHES, FAILING INITIAL STERILITY TESTS. THIS PROCEDURE WAS IN VIOLATION OF THE FIRM'S FORM 6 AND COULD RESULT IN BATCH NON-STERILITY.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED THE TELEGRAM DATED DECEMBER 8, 1975 FROM THE FIRM REQUESTING THAT THE AFFECTED LOTS OF THE 500 MG AND 1 GRAM STRENGTHS OF THE PRODUCT BE RECALLED.

3. FOREIGN CONSIGNEES AS FOLLOWS:

P.T. SQUIBB, INDONESIA
P.O.BOX 2760
JAKARTA, INDONESIA

SQUIBB (FAR EAST LTD.)
SHELL HOUSE
10TH FLOOR
HONG KONG, BRITISH CROWN COLONY. ROBINSON

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: FOOD & DRUG REGULATIONS, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 01 JAN 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976STATE000198
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA:JRWEINROTH MD
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750452-0392
From: STATE
Handling Restrictions: n/a
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ISecure: 1
Legacy Key: link1976/newtext/t19760191/aaaadcx.tel
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Margaret P. Grafeld
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04 MAY 2006

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Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY-VOLUNTARY RECALL, LACK OF ASSURANCE OF STERILITY
TAGS: OGEN, ETRD, TBIO, ID, HK, FDA, P T SQUIBB
To: JAKARTA HONG KONG
Type: TE
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